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GE Healthcare

K042866

Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).

Submitter:	GE Medical Systems PO Box 414 Milwaukee, WI 53201
Contact Person:	D. Duersteler Safety and Regulatory Engineering Telephone: 262-312-7029; Fax: 262-312-7144
Date Prepared:	September 13, 2004
Device Name:	AMX5 and AMX 5D Mobile X-ray Systems Mobile X-ray System, 21CFR892.1720 (90IZL)
Marketed Device:	AMX4 Plus Mobile X-ray system described in 510(k) No. K021016, currently in commercial distribution.

Device Description: The AMX5 is a power driven mobile unit including an X-ray control, X-ray generator, X-ray tube, and beam limiting device, along with control electronics for the drive mechanism, and embedded software. The AMX5D is the same as the AMX5 but is used in conjunction with a portable digital X-ray detector.

Indications for Use: The AMX5 and AMX5D are indicated for use in generating radiographic images of human anatomy in all general purpose X-ray diagnostic procedures. It may be used in radiology departments, emergency rooms, intensive care units, operating rooms, pediatrics, orthopedics, and clinics.

Comparison with Predicate Device: The AMX5 and AMX5D are of a comparable type and substantially equivalent to the currently marketed AMX4 Plus Mobile X-ray system. They have the same technological characteristics and are comparable in key safety and effectiveness features. They use the same basic design, construction, and materials, and have the same intended uses as the predicate device.

Summary of Studies: The device has been evaluated for electrical, mechanical, and radiation safety, and conforms with applicable medical device safety standards.

Clinical Tests: None required.

Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The AMX5 and AMX5D have the same intended uses; incorporate the same technology; and use similar design, construction, materials, and features as the legally marketed AMX 4 Plus Mobile X-ray system. The devices conform to applicable medical device safety standards and compliance is verified through independent evaluation with factory surveillance. Therefore, it is the opinion of GE Medical Systems that the AMX5 and AMX5D Mobile X-ray Systems are substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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GE Healthcare Technologies
% Mr. Tamas Borsai
Division Manager, Medical Division,
and Program Manager, Third Party
Review Program
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K042866
Trade/Device Name: AMX5 and AMX5D
Mobile X-ray Systems
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: 90 IZL
Dated: October 14, 2004
Received: October 18, 2004

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K042866

Device Name: AMX5 and AMX5D Mobile X-ray Systems

Indications for Use

The AMX5 and AMX5D are indicated for use in generating radiographic images of human anatomy in all general purpose X-ray diagnostic procedures. It may be used in radiology departments, emergency rooms, intensive care units, operating rooms, pediatrics, orthopedics, and clinics.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Use _____ OR Over-The-Counter Use_____
(Per 21 CFR 801-109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042866